UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,172	04/02/2004	Donald P. Bushby	Plantar Fasciitis	3082
61226 7590 05/07/2007 JOHN K. BUCHE			EXAMINER	
7777 FAY AV	ENUE	PATEL, TARLA R		
SUITE 205 LA JOLLA, CA 92037			ART UNIT	PAPER NUMBER
		3772		
			MAIL DATE	DELIVERY MODE
			05/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

)e					
int(s)	٦				
Y, DONALD P.					
t l	1				
ndence address	1				
HIRTY (30) DAYS,					
date of this communication. 2. § 133). e any					
as to the merits is 213.					
r. 1.85(a). See 37 CFR 1.121(d). or form PTO-152.					
).					

	Application No.	Applicant(s)				
	10/817,172	BUSHBY, DONALD P.				
Office Action Summary	Examiner	Art Unit				
	Tarla R. Patel	3772				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
 Responsive to communication(s) filed on 12 March 2007. This action is FINAL. 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. 						
Disposition of Claims						
4) Claim(s) 1-43 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-43 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	te				

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)

DETAILED ACTION

Information Disclosure Statement

The Information disclosure statement (IDS) submitted on 10/03/05 is acknowledged by Examiner. The IDS meets the requirements of 37 CFR 1.97 and 1.98 and therefore the references there in have been considered.

Claim Objections

1. Claims 10 and 19 are objected to because of the following informalities: The claims do not end in a (.) and as a result it is unclear if there are more limitations or if the claim should end as they stand.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-5, 9 and 12-13 rejected under 35 U.S.C. 102(e) as being anticipated by Burgess (6,640,465).

4. Burgess discloses a method for managing stress on a plantar fascia of a human foot providing a support device (110) which is preshaped (column 2 lines 38-40) to be conformed for use with the foot adhering (fig 2) at least a portion of said support device to the foot using an adhesive (120) and controlling tension in at least a portion of the plantar fascia of the foot. The step of controlling includes sharing the tensile forces applied to the plantar fascia from the forces on an arch of the foot which push the bones of the foot downwardly, said sharing being among the plantar fascia and said support device (see fig 2). As required by claim 9 and 12 the support device also includes a protective cover, which is removably adhered to adhesive (column 4 lines 49-55).

With respect to claims 2 and 3 the step of adhering at least a portion of said support device includes applying said support device with adhesive to the foot and pressing support device to the foot (see fig 2). As required by claim 4, the support is substantially stretch resistant since the device does not come off while walking or running (column 3 lines 52-55) and can be made of resilient material.

With respect to claim 5 the support is made of less than 30 mils (column 3 lines 13-15).

Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claims 1-9,12-18 and 20-36, 39-43 rejected under 35 U.S.C. 103(a) as being unpatentable over Turtzo (Application No.09, 875,357) in view of Burgess (465).

Turtzo substantially discloses a method for managing stress on a plantar fascia of a human foot including a support device (24) which is preshaped to be conformed for use with the foot adhering at least a portion of said support device to the foot controlling tension in at least a portion of the plantar fascia of the foot. The step of controlling includes sharing the tensile forces applied to the plantar fascia from the forces on an arch of the foot which push the bones of the foot downwardly, said sharing being among the plantar fascia and said support device (see fig 4).

Turtzo further discloses device with straps for front, arch and heel area (14,44), where in straps can be applied an adhesive for securing around the portions of the foot (0030) as required by claims 7-8 and 31-32.

- 7. However Turtzo does not disclose the adhesive on support means to adhere to bottom of the foot and foot support having thickness of less than 30 mils. However Burgess teaches a support device having an adhesive and foot support having thickness of less than 30 mils (column 3 lines 13-15). Burgess further teaches a removable protective (column 4 lines 49-55) covering on top of the adhesive. At the time of the invention, it would have been an obvious to one skilled in art to have modify the device of Turtzo as taught by of Burgess to adding adhesive to device to have more adherence to foot and be able to use it with stocking, socks and inside the shoe.
- 8. Turtzo also does not teaches the support device is made of permeable material, which helps transporting moisture from a surface of the foot and further requires the device made of Rayon fabric.

 However Burgess teaches a foot support device made of fibrous layer may be synthetic fibers, such as polypropylene fibers, or natural fibers, such as paper or cloth fibers (column 4 lines 4-8). One skilled in art would understand that natural fibers transport moisture from a surface of the foot

and also to interpret synthetic fibers, such as Rayon fabric, to have smoother fit to surface of foot and have wicked away the moisture from sweat of foot.

With respect to claims 21-23, 25-27 examiner interpreted that by securing the device on user's foot Turzto results in treating pain in at least one of the heel, or arch or ball of the foot (0016 and 0027) and controls step to prevent extension and stretching, reduce tension on the plantar fascia of the foot.

- 9. As required by the claims 24 and 28 Turtzo substantially disclose the invention as claimed. Turtzo does not disclose the support device is made of a plurality of materials, which are substantially stretch resistant.

 However Burgess teaches the support device can be made of various materials to form the resilient device. At the time of the invention, it would have been an obvious to one skilled in art to interpret the various as plural materials to have modified the device of Turtzo to have more flexibility into making the device and have better stretch resistant device for the user.
- 10. Claims 10 and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Turtzo and Burgess as applied to claims 1-9,12-18 and 20-36, 39-43 above, and further in view of Shaw (5,897,518).

Turtzo and Burgess substantially disclose the invention as claimed; see rejection to claims 1-9,12-18 and 20-36, 39-43 above. Turtzo and Burgess do not disclose support devices that include indicia that indicate the order in which portions of said support device are attached to the foot. However Shaw teaches a support device that has indicia that to help center the device under the arch of the feet (column 2 lines 18-20). At the time of the invention, it would have been an obvious to one skilled in art to use the indicia of Shaw with the device of Burgess and Turtzo to ensure that the user properly applies the device to their foot.

11. Claims 37-38 rejected under 35 U.S.C. 103(a) as being unpatentable over Turtzo and Burgess as applied to claimed claims 1-9,12-18 and 20-36, 39-43 above, and further in view of and Dalton (2004/0118017).

Turtzo and Burgess substantially disclose the invention as claimed; see rejection to claims 1-9,12-18 and 20-36, 39-43 above. Turtzo and Burgess do not disclose a support device that includes medicinal additives, antifungal treatments, anti-microbial treatments, anti-inflammatory treatments, deodorants, and tea tree oil.

However Dalton teaches a support device having an insole that is treated with antibacterial agent (0031). At the time of the invention, it would have

Application/Control Number: 10/817,172 Page 8

Art Unit: 3772

been an obvious to one skilled in art to treat the support device of Turtzo and Burgess with antibacterial agent to avoid odor causing bacteria and fungus.

Response to Arguments

- 12. With respect to Applicant's arguments that Burgess does not teach a "method for managing stress on a plantar fascia" and "controlling tension in at least a portion of the plantar fascia of the foot, wherein said tension is shared between the plantar fascia and said support device", the examiner respectfully disagree. Burgess is clearly capable to provide the function of controlling tensile forces, since the Burgess's device has a support device that is made of a stretch resistant material and is applied to the bottom of the foot by an adhesive. Further, applicant has not set forth any specific structural elements to provide for the "controlling tension in at least a portion of the plantar fascia of the foot".
- 13. Applicant also argues that one sidled in the art would not have combined Turtzo and Burgess because to do so would teach away from Applicant's's invention and because there was no motivation in the references to make such a combination because Turtzo teaches a splint and Burgess never mentions a splint. Applicant further argues that Turtzo's

Art Unit: 3772

splint is not configured to be placed under the socks. Applicant's claims are directed to a support device and method for managing stress on a foot wherein the device is claimed having a foot sole support that is, at least in part, pre-shaped for application to the sole of the foot and the device includes at least one strap to wrap across the foot. While Turtzo does disclose the invention using the term "splint" it is still employed to provide support for the foot for treatment of plantar fascitis. Applicant's claims are constructed with "comprising" language which is an open claim construction and, as such, does not preclude the Turtzo device from meeting the claim limitations. Turtzo teaches a device that is capable of providing support to the plantar fascia area of the foot and thereby will control tensile forces. Further, applicant has not set forth any specific structural elements that would teach away from a more "bulky splint" as applicant asserts in their response (see page 15 of arguments). In the rejection of record, Turtzo is modified by Burgess to provide a removable protective support for use with the splint of Turtzo. Regarding applicant's arguments that the Burgess device is for a different purpose, the examiner respectfully points out that although the intended purpose of the Burgess device is to protect the foot

Art Unit: 3772

from exposure, it does not preclude other uses. The device of Burgess is capable of being attached to the foot via the splint of Turtzo.

- Applicant further argues that a prima facia case of obviousness was 14. not made against claims 10 and 19 under the rejections of Turtzo and Burgess and in further view of Shaw. Specifically, applicant argues that Shaw does not provide indicia that indicates the order in which portions of the support device are attached to the foot. The examiner respectfully disagrees. The device of Shaw is disclosed to indicia, such as lines, to center the device onto the foot. Claims 10 and 11 require that the indicia indicate the order in which the device is attached to the foot. It is the position of the examiner that it would be obvious to one skilled in the art to recognize that a user will use the lines on the device of Shaw to provide an indication as to apply that portion of the device to the foot first and then it would be obvious that the other portions of the device would be attached after.
- 15. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into

Art Unit: 3772

account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). A reference is to be considered not only for what it expressly states, but for what it would reasonably have suggested to one of ordinary skill in the art. One cannot show non-obviousness by attacking the references individually where the rejection is based on a combination of references. The examiner recognizes that the references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of references. However, there is no requirement that a motivation to make the modification be expressly articulated.

16. Applicant further argues that a *prima facia* case of obviousness was not made against claims 37-38 under the rejections of Turtzo and Burgess and in further view of Dalton. Specifically, applicant argues that Dalton does not teach limitations of the present application because Dalton is an *insole* and that an insole is to be within a shoe, not secured to a foot. Regarding applicant's arguments that the Dalton device is for a different

Art Unit: 3772

purpose, the examiner respectfully points out that although the intended purpose of the Dalton device is an insole, it does not preclude other uses.

The device of Dalton is capable of being attached to the foot via the spent of Turtzo.

17. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). A reference is to be considered not only for what it expressly states, but for what it would reasonably have suggested to one of ordinary skill in the art. One cannot show non-obviousness by attacking the references individually where the rejection is based on a combination of references. The examiner recognizes that the references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of references.

However, there is no requirement that a motivation to make the modification be expressly articulated.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3772

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tarla R. Patel whose telephone number is 571-272-3143. The examiner can normally be reached on M-F 6-3.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 3772

TP

PATRICIA BIANCO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

4-30-07

Page 15